

an inflatable dilatation balloon on the distal shaft section having an interior which is in fluid communication with the second inner lumen; and

e) a proximal shaft section much longer than the distal shaft section which is a single elongated tubular member with two inner lumens extending therein, one of the two inner lumens being in fluid communication with the second inner lumen in the distal shaft section and the other inner lumen being in fluid communication with the third inner lumen in the distal shaft section.

REMARKS

The applicant wishes to thank the Examiner for the courtesies extended to counsel during the personal interview held on November 16, 1994. The Examiner Interview Summary Record accurately reflects the substance of the discussions during the interview.

In the aforesaid Office Action the Examiner rejected applicant's claim 18 under 35 U.S.C. §102(b) as being anticipated by or under 35 U.S.C. §103 as being unpatentable over Enzmann *et al.* Claims 23 and 26-27 were rejected under 35 U.S.C. §102(b) as being anticipated by or under 35 U.S.C. §103 as being unpatentable over Gants. Claim 24 was rejected under 35 U.S.C. §103 as being unpatentable over Nordenstrom (1965). Claims 25 and 28 were rejected under 35 U.S.C. §103 as being unpatentable over Weikl *et al.* Claims 28-29 were rejected under 35 U.S.C.

§103 as being unpatentable over Gants. Claims 24-26 and 28 were rejected under 35 U.S.C. §103 as being unpatentable over the Bonzel publication.

In response the applicant has amended the claims to obviate the rejections under 35 U.S.C. §112 and to clarify the invention over the cited references.

With respect to the rejection of claim 18 based upon the Enzmann *et al.* reference, the applicant wishes to note that device of Enzmann is an introducer assembly and, as such, it is unable, to be advanced to and within a patient's coronary artery. As indicated in column 12, lines 43-65, of Enzmann, the short guidewire 64 of Fig. 15 is used only to introduce the catheter 51 (sometimes identified by reference number 50) into the patient's blood vessel and once the catheter is introduced, the short guidewire is removed. The catheter, which is much longer than the guidewire (see column 4, lines 41-43 of Enzmann), is then advanced without the aid of the guidewire into the patient's superior vena cava. In contrast, with the device of the present invention, the guidewire must be sufficiently long to be able to be passed through the patient's femoral artery and beyond the location in the patient's coronary artery where the procedure is to be performed and is longer than the catheter. This is necessarily so because the catheter is advanced over the guidewire to the vascular site of the procedure which usually requires the guidewire to extend beyond the vascular site. The purpose of the invention is to more easily advance and withdraw a catheter over a guidewire and the Enzmann patent is not relevant

to this purpose. Both the catheter and guidewire in claim 18 must be of sufficient length to be advanced into the patient's coronary artery where the procedure is to be performed. The Enzmann patent does not describe this and therefore cannot anticipate this claim. Additionally, because the Enzmann patent does not pertain to the advancement of a catheter over a guidewire to a desired location within the patient's vasculature with the guidewire being longer than the catheter, the reference can in no way suggest the claimed invention.

Claims 23 and 26-27 stand rejected over the Gants reference. However, the device described in this reference is designed to block off both ends of a patient's urethral canal for purposes of positive pressure urethrography. Neither the balloon 16 or the balloon 28 of the Gants device are designed to be inflated within a patient's body lumen. Balloon 16 is inflated within the patient's bladder and then pulled against the distal urethral opening to occlude the opening. Balloon 28 of Gant is configured to be pressed against the patient's external meatus and then be inflated to block off the external opening of the urethra. The balloon 28 is specifically provided with a large flat bottom 34 so that it cannot be inserted into the urethra (see column 3, lines 32-37). During the interview, the Examiner speculated that the balloon 28 of Gant could be inserted into a patient's artery. However, as shown in Fig. 1 and described in column 1, lines 44-46, even when the balloon 28 is deflated, it has a large flat distal face which would preclude advancement into a patient's vasculature. Thus, in view of

the fact that the balloon unit 24 is configured to prevent its use as an intraluminal device, it clearly cannot be used as an intravascular catheter or a balloon dilatation catheter as proposed by the Examiner.

In the rejection based upon the Gants patent, the Examiner apparently equates catheter (10) of Gants to a guidewire because the catheter is disposed within the inner lumen of balloon unit (24) and the balloon unit is advanced over the catheter shaft. However, a catheter is not a guidewire, even though it may perform a guiding function, so in Gants there is no teaching of a guidewire slidably disposed within the inner lumen of a catheter as required by the present claims. Indeed, balloon unit (24) is also not a catheter as this term is normally used by those skilled in the art because it is not designed to be advanced into a body lumen or cavity. Thus, it should be clear that the Gants reference does not teach every feature of the rejected claims and therefore, it cannot anticipate these claims. The reference likewise does not suggest the use of a guidewire as required by the claims because replacing the catheter (10) of the Gants device with a guidewire, as suggested by the Examiner in the rejection, would result in an assembly with no distal balloon to close off the distal urethral opening, the very purpose of the Gants device. The law is well settled that such a modification of a reference in a 103 rejection is improper. However, even if the catheter (10) of Gants is replaced with a guidewire, the device still would not meet the language of the rejected claims because the balloon unit (24) could not be advanced into the patient's artery to perform a

procedure and the balloon unit is incapable of performing an intravascular procedure.

The Nordenstrom (1965) reference, which was used by the Examiner to reject claim 24, describes two different catheters, one for use in the right ventricle or venous side and one for the left ventricle or the arterial side. The catheter designed for the venous side has means to perform a vascular procedure (delivery of contrast fluid) proximal to the proximal guidewire port, not between the proximal and distal guidewire ports as called for in claim 24 as amended above. The catheter of Nordenstrom (1965) which was designed for use in the arterial system did not have guidewire ports because the catheter was not intended to be used with a guidewire, it has neither a short guidewire lumen in the distal portion nor guidewire ports in communication with the inner lumen. Therefore, the arterial catheter is not a rapid exchange type catheter. Neither of the prior art devices described in the Nordenstrom (1965) reference has the essential features of the invention as required by claim 24 and neither of the devices of this reference teaches or suggests the present invention. In fact, this reference leads those skilled in the art away from the present invention because the device described in this reference for use on the venous side was found to be unsuitable for arterial use, the use to which the present invention is specifically directed, and the device described for the arterial side had none of the features of the present claims.

The Examiner's rejection of claims 25 and 28 based upon the Weikl *et al.* reference is believed by the applicant to be unsupported. Claim 25 requires a guidewire to be disposed within the patient's vasculature with the distal end of the guidewire extending beyond the location where the angioplasty procedure is to be performed with a proximal portion extending out of the patient. The dilatation catheter is mounted on the proximal portion extending out of the patient and advanced over the guidewire until the balloon on the catheter is positioned at the desired location where the procedure is to be performed. Weikle *et al.* employs no guidewire and, moreover, the reference is silent as to when or how the sliding member (14) is advanced over the treatment catheter (1), so this reference cannot teach mounting the catheter on the proximal portion of the guidewire which extends out of the patient as called for by claim 25.

The invention of claim 28 is directed to the invention which is embodied in the device of Figs. 5-9 of the present application. In this embodiment, the proximal shaft has two lumens, one for directing inflation fluid to the interior of the balloon and the other, which extends to the distal tip of the catheter, for taking pressure measurements and the like through a second port provided in the distal end of the catheter. Weikle *et al.* does not suggest this embodiment. The Examiner contends that one of the lumens 12 or 13 of the treatment catheter I in the Weikle *et al.* device could be located in the shaft 16 of the sliding member 14, but provides no line of reasoning why this change should be made and more importantly how this change

could be made. The sliding member 14 of Weikle *et al.* has a sealing sleeve or element 18 to contain the fluid and debris within the chamber between the two occluding balloons. There is no suggestion as to how an additional conduit or lumen can be introduced into the sliding member 14 of Weikle to provide fluid communication with the chamber defined between the balloons 4' and 5'. The Examiner speculates that one of the lumens 12 or 13 "would" be located in the shaft 16 in the Fig. 3 embodiment but provides absolutely no support for such a conclusion. The only location taught or suggested by the reference is within the interior of the treatment catheter 1. There is no reason to put these lumens at a different location and none is suggested by the Examiner.

The rejection of claims 28 and 29 based upon Gants is likewise unsupported. The Examiner contends that it would be obvious to include an additional lumen to provide additional fluid infusion. However, the Examiner loses sight of the purpose of the balloon 20 which is connected to the shaft 32 in Gants. Balloon 20 is used to block the exterior meatus so that fluid can be introduced into the urethral canal of the patient through port 40 in the catheter 10 to detect suburethral diverticula. It is not clear how or why additional fluid infusion could be used in conjunction with balloon 20. The only fluid needed is for inflating the balloon. In the absence of any need or suggestion to add an additional lumen, applicant submits that the Gants reference fails to suggest the present invention and that the claims directed to this invention are clearly patentable over this reference.

As to the rejection of claims 24-26 and 28 based upon the Bonzel publication, the applicant wishes to reassert the Rule 131 Declaration filed in the parent application swearing behind the same reference. The rejected claims are clearly supported in the evidence presented with the previously submitted Rule 131 Declaration and therefore the Bonzel reference is not a valid prior art reference against these claims. As to the rejection of claim 28, the applicant wishes to note that there is no suggestion in the brief disclosure of Bonzel to add another lumen and there is no need, expressly or implicitly disclosed in the publication, for additional fluid infusion which the Examiner presents as speculation. The only such suggestion is found in applicant's specification.

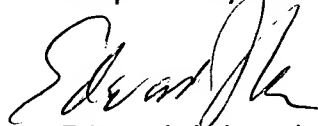
As to the rejections under 35 U.S.C. §103, while the applicant does not believe that a prima facie case has been demonstrated, applicant has submitted concurrently herewith a Rule 132 Declaration attesting to the commercial success of products covered by the presently pending claims. The declaration shows that the sales of dilatation catheters of the present invention in the United States now amount to about 42% of the total dilatation catheter market in the United States. Moreover, of the top 20 highest selling balloon dilatation catheters in the United States, the first, second and sixth ranked catheters fall within the scope of the presently pending claims. This demonstrates a substantial appreciation of the present invention by the market place.

Regarding the rejection of claims 26 and 27 under 35 U.S.C. §112 (second paragraph), please note that a guidewire is not a positive element of claim 26 and the "has with the" has been deleted.

Applicant has also filed concurrently herewith a terminal disclaimer to avoid the double patenting rejection.

Applicant submits that the presently pending claims of this application define patentable subject matter and respectfully requests reconsideration and an early allowance of these claims.

Respectfully submitted,



Edward J. Lynch
Attorney for Applicant
Registration No. 24,422

Attachment: Terminal Disclaimer
Rule 132 Declaration

CROSBY, HEAFEY, ROACH & MAY
1999 Harrison Street
P.O. Box 2084
Oakland, CA 94604-2084

Telephone: (510) 466-6805
Facsimile: (510) 273-8866

EJL/bc